UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

No. 16 Civ. 4226 (RJS)

BIOCAD, JSC,

Plaintiff,

VERSUS

F. HOFFMAN-LA-ROCHE, LTD., *ET AL.*,

Defendants.

OPINION AND ORDER
September 30, 2017

RICHARD J. SULLIVAN, District Judge:

Plaintiff Biocad JSC brings this action against Defendants Roche Holding AG, F. Hoffman-La Roche Ltd., Genentech, Inc., and R-Pharm JSC, alleging that Defendants engaged in anti-competitive conduct to preclude Plaintiff from entering the market for oncological drugs in the United States. Now before the Court are Defendants' motions to dismiss the First Amended Complaint pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6). (Doc. Nos. 51, 53, 56.) For the reasons set forth below, the motions are GRANTED.

I. BACKGROUND

A. Facts

Plaintiff is a Russian drug development and manufacturing company with its principal place of business in St. Petersburg, Russia.[1] Defendants Roche Holding AG and F. Hoffman-La Roche ("FHL Roche") are Swiss corporations based in Basel, Switzerland engaged in the research, production, distribution, and sale of pharmaceuticals. Defendant Genentech, Inc. is a Delaware corporation affiliated with FHL Roche and Roche Holding AG (together, the "Roche Group") with its principal place of business in San Francisco, California. Defendant R-Pharm JSC is a Russian pharmaceutical company with its

---

[1] The following facts are taken from the First Amended Complaint (Doc. No. 37 ("FAC")) and are accepted as true for the purpose of deciding this motion. The Court has also considered Defendants' memoranda in support of dismissal (Doc. Nos. 52, 55, 57), Plaintiff's opposition (Doc. No. 63 ("Opp'n")), and Defendants' reply memoranda (Doc. Nos. 65–67).

principal place of business in Moscow, Russia.

The First Amended Complaint alleges an elaborate conspiracy whereby the Defendants[2] engaged in illegal anti-competitive behavior in Russia in order to sabotage Plaintiff's nascent efforts to enter the U.S. market for oncology drugs. Plaintiff alleges that Defendants maintain a monopoly in the United States over certain treatments called monoclonal antibodies, and in particular, over three drugs: bevacizumab (Avastin), trastuzumab (Herceptin), and rituximab (Rituxan) (collectively, the "Drugs"). Plaintiff further alleges that it is the only pharmaceutical company in the world able to manufacture biosimilars of the Drugs and thus compete directly with Defendants in the United States and in other countries. (FAC ¶¶ 56, 63.) Biosimilars are drugs sold at prices lower than their brand-name equivalents. (*Id.* ¶¶ 82–84.)

Plaintiff alleges that it began developing biosimilar monoclonal antibodies in 2010, including biosimilars of the Drugs, and received approval from the Russian Ministry of Health for its biosimilars of the Drugs in late 2014 and 2015. (*Id.* ¶¶ 58–62.) Plaintiff has two production sites for its drugs in Russia, one in St. Petersburg and one in Moscow, and has "contracts for the sale and delivery of its biosimilars valued at over U.S. $200 million, with distribution partners in Indonesia, Turkey, Armenia, Cambodia, Kenya, Kyrgyzstan, Morocco, Myanmar, Pakistan, South Africa, Ukraine, Uzbekistan, [Sri] Lanka, and Vietnam." (*Id.* ¶¶ 64, 67.) Plaintiff alleges that it has begun taking steps to market its biosimilars in the United States by opening a subsidiary and hiring personnel in the United States, securing a lease for space to be used as a laboratory, budgeting the cost of entry into the U.S. market, opening a new manufacturing site in Eastern Europe, hiring consultants to help ensure that the new site meets U.S. Food and Drug Administration ("FDA") and European Union regulations, developing a Quality Improvement Plan to meet FDA requirements, and spending over $7 million on equipment and incidental fees. (*Id.* ¶¶ 68–71, 74–80.) Plaintiff "anticipates FDA approval to sell biosimilars in the U.S. and plans to compete head to head against [Defendants] by dramatically undercutting" Defendants' prices for the Drugs. (*Id.* ¶ 80.)

However, according to the First Amended Complaint, Defendants' illegal and anti-competitive conduct in Russia has hampered Plaintiff's plans to enter the U.S. market for the Drugs. Plaintiff alleges that Defendants perpetrated an assortment of illegal, anticompetitive schemes, including:

- Engaging in predatory pricing by increasing the prices of the Drugs in the United States and decreasing the prices of the Drugs in Russia by 72% to 84% (*id.* ¶¶ 121–27);

- Selling the Drugs in Russia through a distributor (Defendant R-Pharm) at a loss (*id.* ¶¶ 128–35);

- Bribing doctors, pharmacies, and hospitals in Russia to prescribe and request the Drugs from state-sponsored insurance programs (*id.* ¶¶ 136–80);

- Limiting distribution of the Drugs in order to thwart testing of biosimilars (*id.* ¶¶ 181–91);

[2] The First Amended Complaint rarely distinguishes between the acts of each Defendant, and frequently refers to all four Defendants simply as "Defendants," or to the Roche Group as "Roche." (*See, e.g.*, FAC ¶ 4 n.1, 9, 11, 13.)

- Illegally tying and bundling the drug Herceptin to another cancer drug, Perjeta, in Russia (*id.* ¶¶ 192–205);

- Making fraudulent bids for and misrepresenting the availability of Avastin in Russia (*id.* ¶¶ 206–14); and

- Packaging Herceptin in a way that forced patients to buy, and eventually discard, more of the drug than they would if it was packaged differently (*id.* ¶¶ 215–22).

The First Amended Complaint alleges that the above-described anti-competitive conduct was part of an effort "to foreclose the U.S. market to biosimilar alternatives" to the Drugs. (*See, e.g.*, *id.* ¶ 226.) Plaintiff alleges that, because of Defendants' actions, it has been "deprived of the ability to realize its substantial investments into the preparations undertaken to import biosimilars in[to] the U.S." (*Id.* ¶ 230.)

B. Procedural History

Plaintiff commenced this action by filing a complaint against Defendants FHL Roche Ltd., Genentech, Inc., and R-Pharm JSC on June 7, 2016. (Doc. No. 1.) On October 24, 2016, Plaintiff filed the First Amended Complaint, adding Roche Holding AG as a Defendant and asserting claims under the Sherman Act, 15 U.S.C. §§ 1, 2, the Clayton Act, 15 U.S.C. §§ 15, 26, the Robinson-Patman Act, 15 U.S.C. § 13, and the Donnelly Act, N.Y. Gen. Bus. Law § 340 *et seq.* (Doc. No. 37.) On December 12, 2016, each Defendant filed a motion to dismiss the First Amended Complaint (Doc. Nos. 51–58) arguing, among other things, that Plaintiff did not allege an antitrust injury and therefore lacks antitrust standing to bring a claim,[3] that the Court lacks subject-matter jurisdiction over Plaintiff's Clayton Act and Robinson-Patman Act claims, and that the Foreign Trade Antitrust Improvements Act of 1982 ("FTAIA") bars Plaintiff's Sherman Act and Donnelly Act claims.[4] The motions were fully briefed by February 15, 2017.

II. Legal Standard

On a Rule 12(b)(1) motion to dismiss, the party seeking to invoke the Court's jurisdiction bears the burden of proving that subject matter jurisdiction exists. *Robinson v. Overseas Military Sales Corp.*, 21 F.3d 502, 507 (2d Cir. 1994). "A case is properly dismissed for lack of subject matter jurisdiction under Rule 12(b)(1) when the district court lacks the statutory or constitutional power to adjudicate it." *Makarova v. United States*, 201 F.3d 110, 113 (2d Cir. 2000). In deciding a motion to dismiss a complaint pursuant to Rule 12(b)(1), "[t]he court must take all facts alleged in the [pleading] as true and draw all reasonable inferences in favor of [the claimant]." *Morrison v. Nat'l Australia Bank Ltd.*, 547 F.3d 167, 170 (2d Cir. 2008) (citation and quotation marks omitted).

[3] Although Defendant Genentech, Inc.'s brief makes reference to Plaintiff's constitutional standing, its arguments and analysis reflect that it is only challenging Plaintiff's antitrust standing.

[4] The Court does not reach Defendants' arguments that Plaintiff failed to state a claim for each of its causes of action, that Plaintiff R-Pharm was not properly served, that the Court lacks personal jurisdiction over R-Pharm, and that the case should be dismissed under the doctrine of forum non conveniens. The Court notes that it may dismiss a complaint without addressing personal jurisdiction in cases "with multiple defendants – over some of whom the court indisputably has personal jurisdiction – in which all defendants collectively challenge the legal sufficiency" of the complaint. *Chevron Corp. v. Naranjo*, 667 F.3d 232, 246 n.17 (2d Cir. 2012).

To survive a motion to dismiss pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, a complaint must "provide the grounds upon which [the] claim rests." *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2d Cir. 2007); *see also* Fed. R. Civ. P. 8(a)(2) ("A pleading that states a claim for relief must contain . . . a short and plain statement of the claim showing that the pleader is entitled to relief . . . ."). To meet this standard, plaintiffs must allege "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). In reviewing a Rule 12(b)(6) motion to dismiss, a court must accept as true all factual allegations in the complaint and draw all reasonable inferences in favor of the plaintiff. *ATSI Commc'ns*, 493 F.3d at 98. However, that tenet "is inapplicable to legal conclusions." *Iqbal*, 556 U.S. at 678. Thus, a pleading that offers only "labels and conclusions" or "a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555. If the plaintiff "ha[s] not nudged [its] claims across the line from conceivable to plausible, [its] complaint must be dismissed." *Id.* at 570.

III. Discussion

A. Plaintiff Has Not Pleaded Antitrust Standing

An antitrust plaintiff must show both constitutional standing and antitrust standing. *Gelboim v. Bank of Am. Corp.*, 823 F.3d 759, 770 (2d Cir. 2016). Although constitutional standing is not implicated here, antitrust standing is "a threshold, pleading-stage inquiry and when a complaint by its terms fails to establish this requirement [a court] must dismiss it as a matter of law." *Gatt Commc'ns Inc. v. PMC Assocs. L.L.C.*, 711 F.3d 68, 75 (2d Cir. 2013) (affirming district court's dismissal of complaint for lack of antitrust standing pursuant to Rule 12(b)(6)).

In order to demonstrate antitrust standing, a plaintiff must allege "(a) that it suffered a special kind of 'antitrust injury,' and (b) that it is a suitable plaintiff to pursue the alleged antitrust violations and thus is an 'efficient enforcer' of the antitrust laws." *Gatt Commc'ns, Inc. v. PMC Assocs., L.L.C.*, 711 F.3d 68, 76 (2d Cir. 2013) (quoting *Port Dock & Stone Corp. v. Oldcastle Ne., Inc.*, 507 F.3d 117, 121 (2d Cir. 2007)). In order to establish antitrust injury, "the plaintiff must demonstrate that its injury is of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful." *In re Aluminum Warehousing Antitrust Litig.*, 833 F.3d 151, 157 (2d Cir. 2016) (quotation marks omitted).

Courts employ a "three-step process for determining whether a plaintiff has sufficiently alleged antitrust injury." *Gatt Commc'ns*, 711 F.3d at 76. First, the plaintiff must identify the anticompetitive practice of which it complains. *See id.* Next, the Court must "identify the actual injury the plaintiff alleges." *Id.* (quotation marks omitted). Finally, because "[i]t is not enough for the actual injury to be causally linked to the asserted violation," the Court must "compare the anticompetitive effect of the specific practice at issue to the actual injury the plaintiff alleges" in order to determine whether the injury alleged is "of the type the antitrust laws were intended to prevent and that flows from that which makes or might make defendants' acts

unlawful." *Id.* (alterations and quotation marks omitted).

Plaintiff contends that its antitrust injury arises from its exclusion from the U.S. pharmaceutical market caused by Defendants' anticompetitive conduct in Russia.[5] However, Plaintiff acknowledges that it does not currently participate, and has *never* participated, in the U.S. market, arguing instead that Defendants illegally "prevent[ed] [it] from engaging in business" there. *Am. Banana Co. v. United Fruit Co.*, 166 F. 261, 264 (2d Cir. 1908), *aff'd*, 213 U.S. 347 (1909). A competitor that has not yet entered a market may also suffer antitrust injury if it was illegally prevented from doing so. *See id.* However, at the very least, such a would-be competitor must demonstrate its "intention and preparedness" to enter the relevant market. *Reaemco, Inc. v. Allegheny Airlines*, 496 F. Supp. 546, 553 (S.D.N.Y. 1980) (quoting *Am. Banana Co.*, 166 F. at 264).

In the context of claims involving entrance into the U.S. pharmaceutical market – a highly regulated industry – Plaintiffs alleging intention and preparedness must demonstrate a likelihood of FDA approval of the would-be competitive drug, since such approval is a prerequisite for any drug to enter the U.S. pharmaceutical market. *See* 21 U.S.C. § 355(a); *Kos Pharm., Inc. v. Barr Labs., Inc.*, 242 F. Supp. 2d 311, 318 (S.D.N.Y. 2003) (FDA approval presents a "significant hurdle" for plaintiff's "prospects for actual sales" of its drug). Courts thus require a plaintiff to allege that FDA approval of the potential drug is at least "probable." *See, e.g., Andrx Pharm., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 808 (D.C. Cir. 2001), *cert. denied*, 535 U.S. 931 (2002) (plaintiff "could have alleged its intent and preparedness to enter the market by claiming that FDA approval was probable"); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 207 (E.D.N.Y. 2003) (finding no antitrust standing when the complaint "does not allege that [plaintiffs] filed an ANDA or that FDA approval was probable") (citing *Andrx Pharm., Inc.*, 256 F.3d at 806–808).

To be sure, not all courts have required that a plaintiff allege that it has received or applied for FDA approval in order establish preparedness to enter the pharmaceutical industry with a particular drug. *Compare Bristol–Myers Squibb Co. v. Copley Pharm., Inc.*, 144 F. Supp. 2d 21, 25 (D. Mass. 2000) (intention and preparedness not demonstrated when plaintiff had not obtained the "tentative regulatory approval required for market entry"), *with Xechem, Inc. v. Bristol-Myers Squibb Co.*, 274 F. Supp. 2d 937, 943 (N.D. Ill. 2003) (declining to find a per se rule requiring a new drug filing with the FDA), *and Bristol-Myers Squibb Co. v. Ben Venue Labs.*, 90 F. Supp. 2d 540, 546 (D.N.J. 2000) (party "need not demonstrate that the FDA has first approved its product" to have standing). However, many of the cases holding that an application for FDA approval is not required to plead preparedness involve claims that FDA applications were delayed or obstructed as a result of allegedly fraudulent

[5] To the extend the FAC can be read to allege injuries in Russia, those injuries do not give rise to an antitrust injury for the reasons set forth in Part B of this opinion. *See, e.g.*, *In re Intel Microprocessor Litig.* 452 F. Supp. 2d. 555, 557 (D. Del. 2006) (dismissing complaint for lack of antitrust standing when it alleged "foreign injuries that occurred in foreign markets" that were "not the type of injury that Congress intended to prevent through the [FTAIA] or the Sherman Act"); *de Atucha v. Commodity Exch., Inc.*, 608 F. Supp. 510, 518 (S.D.N.Y. 1985) ("Congress did not contemplate recovery under the antitrust laws by an individual who traded, and was injured entirely outside of United States commerce.")

patent applications or sham litigation by the defendants – something that is not alleged here. *See, e.g.*, *Rochester Drug Co-op., Inc. v. Braintree Labs.*, 712 F.Supp.2d 308, 317 (D. Del. 2010) (plaintiff alleged that "as a result of [the patent holder]'s scheme, the ANDA approval process was delayed by the FDA"); *In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751, 757 (E.D. Pa. 2003) (plaintiffs "alleged that [d]efendants filed frivolous lawsuits" that "directed resources away from FDA approval and toward the defense of the infringement actions . . . result[ing] in a delay of FDA approval").

But even assuming that a formal application for FDA approval is not required to establish preparedness to engage in the U.S. pharmaceutical market, an antitrust plaintiff must still demonstrate that FDA approval is probable. Consequently, plaintiffs alleging intent and preparedness to enter a pharmaceutical market typically include facts regarding the stage of the FDA-approval process their product has reached or the steps the plaintiff has taken (or plans to take) to secure approval. *See, e.g.*, *Andrx Pharm., Inc.*, 256 F.3d at 807 (approving district court's dismissal of complaint alleging only that plaintiff had filed an Abbreviated New Drug Application, but reversing because the court erred in dismissing with prejudice when the plaintiff may have been able to cure the deficiency); *Retrophin, Inc. v. Questcor Pharm., Inc.*, 41 F. Supp. 3d 906, 915 (C.D. Cal. 2014) (finding sufficient intent and preparedness when plaintiff alleged to have "a plan to obtain regulatory approvals" and an "apparatus to conduct clinical trials to obtain FDA approval") (internal quotation marks omitted); *cf. Brotech Corp. v. White Eagle Int'l Techs. Grp., Inc.*, No. CIV.A.03-232, 2004 WL 1427136, at *6 (E.D. Pa. June 21, 2004) (dismissing counterclaim that failed "to include any allegations regarding how far [plaintiff] has gone in the process of obtaining FDA approval of products . . . [or] when such approval may be anticipated").

Here, Plaintiff has not merely failed to allege that it filed for FDA approval – it has failed to supply any facts whatsoever regarding the FDA approval process for its biosimilars. Plaintiff provides no information about the expected timeline for approval, what clinical trials would be required, whether it has begun conducting clinical trials, its expected FDA application date, whether it has begun preparing an application, whether it has contacted the FDA, whether it has ever obtained approval for other biosimilar drugs from the FDA, or whether its contemplated approval would require a New Drug Application or an Abbreviated New Drug Application. And while Plaintiff alleges that it has audited and inspected one of its facilities in Russia in contemplation of FDA approval, it does not explain the relevance of that *facility* to the approval of its *drugs* in the United States. In sum, Plaintiff has provided little information from which the Court may assess the likelihood of approval of its biosimilars, and has thus failed to allege more than "a hope or expectation" of engaging in the U.S. pharmaceutical market. *Reaemco, Inc.*, 496 F. Supp. at 554 (quoting *Image & Sound Serv. Corp. v. Altec Serv. Corp.*, 148 F. Supp. 237, 239 (D. Mass. 1956)).

Plaintiff places great emphasis on *Xechem, Inc. v. Bristol-Myers Squibb Co.*, 274 F. Supp. 2d 937, for the proposition that it has sufficiently alleged its preparedness to engage the U.S. pharmaceutical market. In that case, like the instant case, the plaintiffs alleged that they had taken various steps to prepare for entry into the U.S. market, including obtaining production and distribution agreements in other parts of the

world. *Id.* at 941–42. However, in *Xechem*, the plaintiffs also alleged that the defendant's anti-competitive conduct – filing fraudulent patents – directly prevented them from applying for FDA approval during the relevant time period. *Id.* at 944 ("Plaintiffs may have been in the position to file for FDA approval with the ANDA as early as 1998, but for Defendant's purportedly fraudulently-obtained patents."). Here, Plaintiff makes no allegation that any of the Defendants' anticompetitive conduct has prevented it from applying for FDA approval, and in fact provides no explanation for its failure to take any steps toward applying for FDA approval to sell its biosimilars in the United States. Plaintiff's emphasis on *Kos Pharm., Inc. v. Barr Labs., Inc.*, 242 F. Supp. 2d at 311, is also unavailing, as that case involved a declaratory judgment for a patent infringement claim, not an antitrust claim, and in any event involved a party that had already applied for FDA approval of the potentially-infringing generic medicine. *See id.* at 317–18.

Although Plaintiff provides other factual allegations relevant to its intent and preparedness to engage the U.S. pharmaceutical market, including that it has created a subsidiary in the United States, leased space in Boston, Massachusetts, and taken steps to ensure that its new facility in Russia is FDA-compliant (FAC ¶¶ 68–71, 75–80), none of these allegations overcome the paucity of facts set forth to demonstrate that FDA approval of Plaintiff's biosimilars is anywhere near likely or "probable." Indeed, Plaintiff's other factual allegations relate principally to its business in Russia and in other parts of the world, not efforts to enter the U.S. market, and in fact underscore its lack of background and experience in the U.S. pharmaceutical market and the absence of contracts to enter the business of selling its biosimilars in the United States.

For these reasons, the Court finds that Plaintiff has failed to set forth facts demonstrating its intention and preparedness to engage the U.S. pharmaceutical market, and thus has failed to allege that it has suffered an antitrust injury. Defendants' motions to dismiss for lack of antitrust standing are therefore granted.

B. The Foreign Locus of Plaintiff's Claims Also Bars This Lawsuit

But even if the First Amended Complaint could clear the bar for antitrust standing, the foreign locus of Plaintiff's allegations would still defeat each of its causes of action. Put simply, (1) the Clayton Act and Robinson-Patman Act do not confer subject-matter jurisdiction over Plaintiff's claims, (2) the FTAIA excludes Plaintiff's allegations from the reach of the Sherman Act, and (3) the Donnelly Act does not extend to claims that are beyond the reach of the Sherman Act. The Court will address each of these conclusions in turn.

1. Plaintiff's Clayton Act and Robinson-Patman Act Claims

The Clayton Act and Robinson-Patman Act provide a private cause of action for illegal tying, price discrimination, and other anticompetitive conduct. However, both acts contain parallel, jurisdiction-limiting language that confines their reach to persons and activities within U.S. commerce, extending only to conduct involving commodities sold for "use, consumption, or resale within the United States," 15 U.S.C. §§ 13 (Robinson-Patman Act), 14 (Clayton Act), and to persons "engaged in commerce," *id.*, a phrase the Supreme Court has determined is "a term of art indicating a limited assertion of federal jurisdiction,"

Circuit City Stores, Inc. v. Adams, 532 U.S. 105, 121 (2001). Specifically, the Supreme Court has held that the reach of both acts is limited "to persons and activities that are themselves 'in commerce,'" *Gulf Oil Corp. v. Copp Paving Co.*, 419 U.S. 186, 194 (1974), as opposed to "anticompetitive acquisitions and activities [that] *affect* commerce," *id*. at 195 (emphasis added); *see also Rotec Indus., Inc. v. Mitsubishi Corp.*, 348 F.3d 1116, 1122 (9th Cir. 2003) ("The reach of the [Robinson-Patman Act] extends only to persons and activities which are themselves within the flow of commerce among the states or with foreign nations, but does not extend to all activities which affect such commerce.").

Plaintiff's illegal tying claim under the Clayton Act, which alleges that Defendants tied and bundled the drug Herceptin to another cancer drug, Perjeta, in Russia, unambiguously pertains only to conduct involving commodities sold in Russia. (*See* FAC ¶ 193 ("[Defendants] organized and orchestrated a classic tying and bundling scheme, where [Defendants] forced Russian cancer patients in need of Perjeta . . . to purchase [Defendants'] Herceptin.")). This claim is not actionable under the Clayton Act, even broadly construed, because it does not involve the purchase or sale of products bound for "use, consumption, or resale within the United States." *See, e.g.*, *Boyd v. AWB Ltd.*, 544 F. Supp. 2d 236, 247 (S.D.N.Y. 2008) (Lynch, J.) (dismissing Clayton Act claim when "[n]othing in the complaint remotely suggests that the transactions . . . involved the purchase or sale of any . . . commodity that was bound 'for consumption, use, or resale within the United States'").

Similarly, Plaintiff's predatory and discriminatory pricing claim under the Robinson-Patman Act, which alleges that Defendants charged prices of 72% to 84% less in Russia than in the United States, likewise depends explicitly upon products sold in Russia. (FAC ¶¶ 124–27). Although one leg of the alleged price discrimination scheme took place in the United States, "no cause of action arises under the [Robinson-Patman] Act unless both commodities involved in the alleged price discrimination are 'sold for use, consumption, or resale within the United States.'" *Zenith Radio Corp. v. Matsushita Elec. Indus. Co.*, 402 F. Supp. 244, 248 (E.D. Pa. 1975) (quoting 15 U.S.C. § 13(a)) (dismissing claims when "one 'leg' of the price discrimination alleged by plaintiffs involves commodities that are 'sold for use, consumption, or resale,' not within the United States, but within a foreign country, Japan"); *see also C.E.D. Mobilephone Commc'ns, Inc. v. Harris Corp.*, No. 81-cv-4651 (JFK), 1985 WL 193, at *2 (S.D.N.Y. Jan. 14, 1985) ("The Robinson-Patman Act, 15 U.S.C. § 13(a), makes it unlawful to discriminate in price between purchasers of like commodities only where such commodities 'are sold for use, consumption, or resale <u>within</u> the United States.'") (emphasis in original).

Plaintiff devotes just three sentences in its 50-page opposition brief to the Robinson-Patman Act, conclusorily asserting that price discrimination between purchasers in different geographic markets may violate the Robinson-Patman Act. (*See* Opp'n at 49–50.) But the cases cited by Plaintiff all involve price discrimination schemes taking place *entirely* within the United States. *See, e.g.*, *Utah Pie Co. v. Cont'l Baking Co.*, 386 U.S. 685, 697, (1967) (discussing price discrimination for frozen pies primarily in Salt Lake City, Utah); *Porto Rican Am. Tobacco Co. of Porto Rico v. Am. Tobacco Co.*, 30 F.2d 234, 235 (2d Cir. 1929) (addressing price discrimination in cigarette sales in Puerto Rico); *Checker Motors Corp.*

v. Chrysler Corp., 283 F. Supp. 876, 881 (S.D.N.Y. 1968), *aff'd*, 405 F.2d 319 (2d Cir. 1969) (discussing legality of rebate program for taxicab purchases in the United States and primarily in New York City). These cases do not address the jurisdictional bar created by the plain language of the Clayton Act and Robinson-Patman Act against suits involving foreign conduct.

Accordingly, the foreign locus of Plaintiff's claims excludes them from the Court's subject-matter jurisdiction under the Clayton Act and Robinson-Patman Act. Those claims are therefore properly dismissed.

2. Plaintiff's Sherman Act Claims

The FTAIA provides that the Sherman Act

> shall not apply to conduct involving trade or commerce (other than import trade or import commerce) with foreign nations unless–
>
> (1) such conduct has a direct, substantial, and reasonably foreseeable effect–
>
> > (A) on trade or commerce which is not trade or commerce with foreign nations, or on import trade or import commerce with foreign nations; or
> >
> > (B) on export trade or export commerce with foreign nations, of a person engaged in such trade or commerce in the United States; and
>
> (2) such effect gives rise to a claim under the provisions of sections 1 to 7 of this title, other than this section.

15 U.S.C. § 6a. Thus, according to the plain terms of the FTAIA, two types of foreign commerce remain subject to the Sherman Act: conduct involving import trade or import commerce, and "conduct involving *nonimport* trade or *nonimport* commerce when that conduct (1) has a direct, substantial, and foreseeable effect on import trade or import commerce, and (2) the Sherman Act claim arises out of that effect." *In re Vitamin C Antitrust Litig.*, 904 F. Supp. 2d 310, 317 (E.D.N.Y. 2012). Courts refer to the first category as the "import exception" and the second as the "domestic effects exception." *See, e.g.*, *id.* at 316.

a. Plaintiff's Claims Do Not Fall Within the Import Exception

When assessing whether allegations fall within the scope of the import exception to the FTAIA, "[t]he relevant inquiry is whether the conduct of the defendants – not the plaintiffs – involves import trade or commerce." *Kruman v. Christie's Int'l PLC*, 284 F.3d 384, 395 (2d Cir. 2002) *abrogated on other grounds by F. Hoffmann-La Roche Ltd. v. Empagran S.A.*, 542 U.S. 155 (2004). Here, the First Amended Complaint alleges foreign acts conducted by one domestic and three foreign Defendants that caused foreign injuries to the Plaintiff and compromised its future plans to import biosimilars of the Drugs to the United States. To the extent the First Amended Complaint makes reference to conduct that allegedly occurred in the United States, it does not allege that those activities caused an injury in the United

States or involved U.S. import commerce.[6] Rather, Plaintiff acknowledges that Defendants' alleged conduct occurred almost exclusively in Russia, but argues that its allegations fall within the import exception because the exception extends to anticompetitive behavior that is "directed at the U.S. import market.'" *In re Vitamin C Antitrust Litig.*, 904 F. Supp. 2d at 316–17.

But while Plaintiff is correct that the import exception does not require "that the defendants function as the physical importers of goods," *id.* (quoting *Animal Sci. Prod., Inc. v. China Minmetals Corp.*, 654 F.3d 462, 470 (3d Cir. 2011), *as amended* (Oct. 7, 2011)), a complaint must still describe conduct that "target[ed] import goods or services." *Animal Sci. Prod., Inc.*, 654 F.3d at 470. Because the import exception is "given a relatively strict construction," *Carpet Grp. Int'l v. Oriental Rug Importers Ass'n, Inc.*, 227 F.3d 62, 72 (3d Cir. 2000), *overruled on other grounds by Animal Sci. Prod., Inc.*, 654 F.3d 462, courts require a close connection between a defendant's alleged conduct and the import trade or import commerce at issue. The import exception thus applies only to foreign anticompetitive conduct "with an immediate impact on U.S. markets." *Maricultura Del Norte v. World Business Capital, Inc.*, 159 F. Supp. 3d 368, 383 (S.D.N.Y. 2015)

Here, Plaintiff has not alleged that Defendants are involved in import commerce, that Plaintiff is importing or has ever imported any product into the United States, or that import commerce for biosimilars of the Drugs even exists in the United States. Instead, Plaintiff argues that its allegation that Defendants' conduct has hampered its *anticipated* participation in *future* import commerce for biosimilars of the Drugs is sufficient. But none of the cases cited in Plaintiff's brief support that proposition, and in fact each case cited by Plaintiff involved at least one party who was engaged in *actual* import commerce. *See, e.g.*, *Eskofot A/S v. E.I. Du Pont De Nemours & Co.*, 872 F. Supp. 81, 83 (S.D.N.Y. 1995) ("[Plaintiff] has average annual sales of approximately $75 million, $12 million of which is derived from sales in the United States."); *In re Vitamin C Antitrust Litig.*, 904 F. Supp. 2d at 317 ("The sale contracts provided by the parties show that defendants specifically contracted for the delivery of vitamin C to locations within the U.S.").

But even if Plaintiff could allege that it was in the business of importing its biosimilars into the United States, which it has not, Plaintiff has not alleged a sufficient nexus between Defendants' conduct and the domestic effects of that conduct to satisfy a "strict construction" of the FTAIA's import exception. That is, the relationship between Defendants' acts and their effect on U.S. import commerce is too attenuated for Defendants' acts to be considered "directed at" a U.S. import market. Rather, Plaintiff's allegations indicate that Defendants' alleged conduct was targeted at the domestic Russian pharmaceutical market, not a U.S.

[6] The First Amended Complaint alleges that Defendants packaged Herceptin "worldwide" in a manner that misrepresents how much patients need to buy or use (FAC ¶ 216), but not that those misrepresentations affected Plaintiff's sales of its biosimilars in the United States, since Plaintiff does not sell drugs in the United States. The First Amended Complaint also alleges that Defendants reduced the number of wholesalers it uses for the Drugs in order to limit the availability of samples necessary for its rivals to obtain FDA approval for competitive drugs, but as noted above, Plaintiff does not allege that it has begun – or even contemplated – clinical trials that require those samples or otherwise attempted to obtain such samples from Defendants. (*See id.* ¶¶ 181–91.)

import market, which is not enough to invoke the FTAIA's import exception.

The Second Circuit's opinion in *Kruman* is particularly instructive in this regard. In *Kruman*, a class of plaintiffs alleged that the defendants participated in a price-fixing scheme for foreign auctions. 284 F.3d at 395. The Second Circuit held that the import exception did not apply, even though some of the items purchased at the foreign auctions were eventually imported into the United States, because "[t]he plaintiffs did not describe conduct by the defendants that was directed at an import market." *Id.* Noting that "the defendants' conspiracy appears to have been directed at controlling the prices they charged for their services in *foreign* auctions," the Circuit concluded that such conduct did not implicate the import exception. *Id.* (emphasis added); *see also id.* at 396 ("[T]he object of the conspiracy was the price that the defendants charged for their auction services, not any import market for those goods."). Here, as in *Kruman*, the conduct alleged in the First Amended Complaint was "directed at" manipulating prices in a foreign country, Russia, and would affect import trade and import commerce into the United States only by a series of indirect and attenuated steps.

Plaintiff's conclusory allegations that the Defendants' scheme "specifically targeted U.S. import and domestic commerce" (FAC ¶¶ 95, 105) and "did in fact produce some substantial effect on the interstate commerce" (*id.* ¶ 224) are unfounded and do not compel a different conclusion. Plaintiff pleads no facts demonstrating such a substantial effect and provides no authority for the proposition that Defendants' alleged *intentions* provide a sufficient causal nexus to satisfy the import exception. On the contrary, *Kruman* clearly requires that action "targeted" or "directed" at import markets for the purposes of the FTAIA must directly affect those import markets, not merely reflect an intention to affect them. *See also Animal Sci. Prod., Inc.*, 654 F.3d at 470 ("Defendants were allegedly involved only in unlawfully setting extra-territorial commission rates. Their actions did not directly increase or reduce imports into the United States.") (quotation marks and citation omitted); *Turicentro, S.A. v. Am. Airlines Inc.*, 303 F.3d 293, 303 (3d Cir. 2002) *overruled on other grounds by Animal Sci. Prod., Inc.*, 654 F.3d at 462 (holding that the import exception was not met when defendant's extraterritorial "actions did not directly increase or reduce imports into the United States"). Here, the only market that Defendants allegedly "targeted" was the Russian market for the Drugs and biosimilars for the Drugs.

Plaintiff's reliance on *Maricultura Del Norte v. World Business Capital, Inc.*, 159 F. Supp. 3d 368, is equally unavailing. In that case, a bank foreclosed upon the plaintiffs' fishing vessels after the plaintiffs, who were bluefin tuna fishers, defaulted on a loan. *Id.* at 372–73. The bank reassigned the loan to the plaintiffs' direct competitor in the fishing industry, which refused to provide the information required to release the vessels in an attempt to eliminate its competition. *Id.* On defendant's motion to dismiss, Judge McMahon held that, because the plaintiffs alleged "an immediate impact on the U.S. bluefin tuna market," the allegations fell within the import exception to the FTAIA. *Id.* at 383. But unlike Plaintiff here, the plaintiffs in *Maricultura Del Norte* were importers who alleged that they "were, are, and intend to continue being sellers of bluefin tuna into the United States market." *Maricultura Del Norte v. World Bus. Capital, Inc.*, 14-cv-10143 (CM) (S.D.N.Y. October 29, 2014), Doc. No. 1 at ¶ 393. In fact, Judge McMahon

distinguished the facts of that case from other cases where the alleged impact on U.S. import commerce was, as here, attenuated by multiple intermediate steps. *Maricultura Del Norte*, 159 F. Supp. 3d at 383.

Unlike the plaintiffs in *Maricultura Del Norte*, and like the plaintiffs in *Kruman*, Plaintiff here does not and cannot allege that Defendants' acts had a direct effect on imports in the United States. Accordingly, Plaintiff's claims do not fall within the import exception to the FTAIA.

b. Plaintiff's Claims Do Not Fall Within the Domestic Effects Exception

Although Plaintiff does not even argue the point, the Court also finds that Plaintiff's claims fail to meet the FTAIA's domestic effects exception because any domestic effect resulting from Defendant's alleged behavior did not "give rise to" Plaintiff's claim under the Sherman Act.[7] Conduct falls within the domestic effects exception when (1) it has a "direct, substantial, and reasonably foreseeable effect" on U.S. domestic, import, or certain export commerce, 15 U.S.C. § 6a(1), and (2) that effect "gives rise to a claim under" the Sherman Act, *id.* § 6a(2). The Supreme Court has held that the statutory phrase "gives rise to a claim" means "gives rise to the *plaintiff's* claim." *See Empagran S.A.*, 542 U.S. at 173 (concluding that "Congress would not have intended the FTAIA's exception to bring independently caused foreign injury within the Sherman Act's reach"). Thus, the domestic effects exception requires two distinct inquiries, "one asking whether the defendants' foreign conduct caused a cognizable domestic effect, and the other asking whether that effect caused the plaintiff's injury." *Lotes Co. v. Hon Hai Precision Indus. Co.*, 753 F.3d 395, 414 (2d Cir. 2014).

Plaintiff essentially alleges that Defendants' conduct in Russia harmed Plaintiff in Russia, which in turn prevented Plaintiff from entering the U.S. market, which in turn will have the eventual domestic effect of driving up the price of the Drugs in the United States. For the reasons discussed above, Plaintiff's attenuated chain of causation is insufficient to establish a "direct, substantial, and reasonably foreseeable effect" under the FTAIA. But even if it could be argued that Defendant's foreign conduct caused a cognizable domestic effect, Plaintiff has not alleged that *this* effect (*i.e.*, increase in the price of the Drugs in the United States) caused *Plaintiff's* injuries as required under the second prong of the domestic effect test. Rather, to the extent there is a causal connection between Plaintiff's injuries and the alleged domestic effect of Defendants' conduct, "the direction of causation runs the wrong way." *Lotes Co.*, 753 F.3d at 414. That is, Plaintiff's injuries caused (or will cause) the domestic effect, not vice versa.

The Second Circuit's opinion in *Lotes* helps to explain the operation of the domestic effects exception in this case. Like Plaintiff here, the plaintiff in *Lotes* alleged that the defendants' foreign anticompetitive conduct excluded it from the U.S. market, which would have the eventual effect of reducing competition and driving up prices. However, the Second Circuit held that the domestic effects exception did not apply because "those higher prices did not cause [plaintiff's] injury of being excluded from the market for USB 3.0 connectors – that injury flowed directly from the defendant's

[7] (*See* Opp'n at 22 ("the relevant inquiry is not the domestic effects exception, but the import exception") (quoting *Maricultura*, 159 F. Supp. 3d at 316).)

exclusionary foreign conduct." *Id.* at 414. The Second Circuit thus clarified that the exception applies only when the domestic effects of a defendant's anticompetitive foreign conduct causes a plaintiff's injury, not when defendant's conduct causes plaintiff's injury, which also results in domestic effects.

Here, Plaintiff's alleged injuries flow from Defendants' allegedly anticompetitive foreign conduct, not the domestic effect of that conduct, and is therefore the type of "independently caused foreign injury" that falls outside of the reach of the domestic effects exception. *Id.* at 414 (quoting *Empagran*, 542 U.S. at 173.)

3. Plaintiff's Donnelly Act Claims

Because Plaintiff's claims are beyond the reach of the Sherman Act, its state-law claim under the Donnelly Act must also be dismissed. The Donnelly Act does not reach foreign conduct deliberately placed by Congress "beyond the Sherman Act's reach." *In re Foreign Exch. Benchmark Rates Antitrust Litig.*, 74 F. Supp. 3d 581, 601 (S.D.N.Y. 2015) (citing *Global Reins. Corp. U.S. Branch v. Equitas Ltd.,* 18 N.Y.3d 722, 735 (2012) (holding that a claim barred by the FTAIA cannot be brought under the Donnelly Act because, among other reasons, "[t]he established presumption is . . . against the extraterritorial operation of New York law . . . and we do not see how it could be overcome in a situation where the analogue federal claim would be barred by congressional enactment")). For the reasons set forth above, Plaintiff's claims are beyond the reach of the Sherman Act. Accordingly, Plaintiff's Donnelly Act claim is also properly dismissed.

C. Plaintiff Is Not Entitled to Injunctive Relief

In an apparent last-ditch effort to secure relief from the Court, Plaintiff makes the conclusory argument that it is entitled to injunctive relief under Section 16 of the Clayton Act because, "[a]t the very least, Plaintiff demonstrated threatened injury of direct exclusion from the U.S. market." (Opp'n at 18.) Section 16 of the Clayton Act confers a private right of action on plaintiffs who allege "threatened loss or damage by a violation of the antitrust laws." 15 U.S.C. § 26. Section 16 injunctive relief is therefore "characteristically available even though the plaintiff has not yet suffered actual injury." *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 130 (1969) (citation omitted). Instead, to state a claim for injunctive relief under Section 16, a plaintiff must merely "demonstrate a significant threat of injury from an impending violation of the antitrust laws or from a contemporary violation likely to continue or recur." *Id.*

But, for the reasons set forth above, Plaintiff has not alleged a "significant threat of injury from an impending violation of the antitrust laws" since it has failed to allege conduct that falls within the reach of U.S. antitrust law. Because the foreign locus of its claims excludes Plaintiff's claims from coverage under that law, there is no "threatened loss of damage" from a violation of those laws alleged here.

D. Plaintiff's Request for Leave to Amend Is Denied

Finally, the Court considers Plaintiff's request for leave to amend. (Opp'n 50.) Although "Rule 15(a) of the Federal Rules of Civil Procedure provides that leave to amend 'shall be freely given when justice so requires,' it is within the sound discretion of

the [Court] to grant or deny leave to amend." *McCarty v. Dun & Bradstreet Corp.*, 482 F.3d 184, 200 (2d Cir. 2007) (quoting Fed. R. Civ. P. 15(a)). In addition, the Second Circuit has consistently stated that district courts may deny leave to amend when plaintiffs request such leave in a cursory sentence on the last page of an opposition to a motion to dismiss, without any justification or an accompanying suggested amended pleading. *See, e.g.*, *City of Pontiac*, 752 F.3d at 188 (affirming denial of leave to amend where plaintiffs already had one opportunity to amend their complaint and had "identified no additional facts or legal theories" to support their request to amend); *Food Holdings Ltd. v. Bank of Am. Corp*., 423 F. App'x 73, 76 (2d Cir. 2011) (affirming district court's denial of leave to amend where plaintiff requested leave to amend "on the final page of their brief in opposition to defendants' motion to dismiss, in boilerplate language and without any explanation as to why leave to amend was warranted"); *Porat v. Lincoln Towers Cmty. Ass'n*, 464 F.3d 274, 275–76 (2d Cir. 2006).

Here, in the final sentence of its opposition to Defendants' motions to dismiss, Plaintiff, without any legal or other support, states in a single sentence that "[e]ven if, *arguendo*, the Court finds any deficiencies in Plaintiff's pleadings in the Amended Complaint, Plaintiff should be afforded the right to correct such deficiencies." (Opp'n 50.) Significantly, Plaintiff offers no basis for its request for leave to amend nor does it attach a proposed amended complaint. *See Loreley Fin. (Jersey) No. 3 Ltd. v. Wells Fargo Sec., LLC*, 797 F.3d 160, 190 (2d Cir. 2015) (noting that a court may deny leave to amend, on notice grounds, "where the request gives no clue as to how the complaint's defects would be cured" (quoting *Porat*, 464 F.3d at 276)). Moreover, this is not Plaintiff's first attempt at re-pleading in this action. To the contrary, on October 24, 2016, after the parties had exchanged pre-motion letters and the Court had held a pre-motion conference concerning Defendants' contemplated motions to dismiss (Doc. Nos. 22, 32), Plaintiff sought and received leave to amend for the purpose of addressing deficiencies in the complaint that the Court and Defendants addressed at some length. Notwithstanding the benefit of Defendants' pre-motion letter and an extensive colloquy with the Court at the pre-motion conference, in which these very deficiencies were discussed (*see* Doc. No. 33 at 12:15–31:14), Plaintiff's amended pleading still fails to allege facts sufficient to withstand a motion to dismiss.

As Judge Lynch aptly noted when he was on the district court, "[w]hile pleading is not a game of skill in which one misstep may be decisive to the outcome, neither is it an interactive game in which plaintiffs file a complaint, and then bat it back and forth with the Court over a rhetorical net until a viable complaint emerges." *In re Refco Capital Mkts., Ltd. Brokerage Customer Sec. Litig*., Nos. 06-cv-643, 07-cv-8686, 07-cv-8688 (GEL), 2008 WL 4962985, at *2 (S.D.N.Y. Nov. 20, 2008) (citations and internal quotation marks omitted); *see also Ruotolo v. City of New York*, 514 F.3d 184, 191 (2d Cir. 2008) (noting that courts can deny leave to amend where there has been "repeated failure to cure deficiencies by amendments previously allowed" (quoting *Foman v. Davis*, 371 U.S. 178, 182 (1962)); *NRW, Inc. v. Bindra*, No. 12-cv-8555 (RJS), 2015 WL 3763852, at *1 (S.D.N.Y. June 16, 2015) ("To grant leave to amend after a plaintiff has had ample opportunity to amend would be condoning a strategy whereby plaintiffs hedge their bets . . . in the hopes of having another bite at the

proverbial apple." (internal quotation marks omitted)). Accordingly, because Plaintiff has failed to attach a proposed amended complaint or even attempted to explain why an additional opportunity to amend would cure the First Amended Complaint's deficiencies, and because Plaintiff's past efforts provide no comfort in this regard, the Court denies Plaintiff's request for leave to amend.

IV. Conclusion

Because Plaintiff has failed to plead an antitrust injury, because the foreign locus of Plaintiff's claims place them outside the reach of U.S. antitrust law, and because Plaintiff has not demonstrated a significant threat of injury from an impending violation of the antitrust laws, Defendants' motions to dismiss the First Amended Complaint are GRANTED, and Plaintiff's request for leave to amend the First Amended Complaint is DENIED. The Clerk of Court is respectfully directed to terminate the motions pending at docket numbers 51, 53, and 56, and to close this case.[8]

SO ORDERED.

RICHARD J. SULLIVAN
United States District Judge

Dated: September 30, 2017
New York, New York

* * *

Biocad JSC is represented by Albert Feinstein and Arevik Khurdayan of Feinstein & Partners PLLC, 54 E. 66th Street, New York, NY, 10065.

F. Hoffman La-Roche Ltd. and Roche Holding AG are represented by Paul Spagnoletti and Andrew S. Gehring of Davis Polk & Wardwell LLP, 450 Lexington Avenue, New York, NY, 10017.

Genentech, Inc. is represented by Amanda P. Reeves, Daniel M. Wall, Lawrence E. Buterman, and Thomas J. Giblin of Latham & Watkins LLP. 555 Eleventh Street, Nw, Suite 1000, Washington, DC, 20004.

R-Pharm JSC is represented by Eric J. Stock of Gibson, Dunn & Crutcher, LLP, 200 Park Avenue, 48th Floor, New York, NY, 10166.

---

[8] Closing this action will not affect Defendants' motion for sanctions (Doc. No. 71), which is still pending before the Court. *See Covanta Onondaga Ltd. P'ship v. Onondaga County Res. Recovery Agency*, 318 F.3d 392, 396 (2d Cir. 2003) ("[A] court that has concluded its adjudication of the merits of a case within its jurisdiction by entering a final judgment retains authority to take action with respect to some collateral matters related to the case, such as attorney's fees and costs.").